

03-17-05

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Date of Deposit March 15, 2005

PATENT

Attorney Docket No.: 015270-006430US

Client Reference No.: 228-US-NEW

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By:



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

John P. Anderson et al.

Application No.: 09/471,669

Filed: December 24, 1999

For: BETA-SECRETASE ENZYME  
COMPOSITIONS AND METHODS

Examiner: Walicka, Malgorzata A.

Art Unit: 1652

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT UNDER 37  
CFR §1.97 and §1.98

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on the attached PTO/SB/08A and PTO/SB/08B forms are being called to the attention of the Examiner. Copies of references 155-184 are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

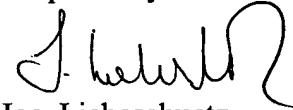
03/18/2005 FMETERKI1 00000104 201430 09471669

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As provided for by 37 CFR 1.97(g) and (h), no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information, and no inference should be made that the information and references cited are, or are considered to be material to patentability because they are in this statement. No inference should be made that the information and references cited are prior art merely because they are in this statement.

This IDS is being filed before the mailing date of the final Office Action or Notice of Allowance. Please charge the IDS fee of \$180 to Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Joe Liebeschuetz  
Reg. No. 37,505

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, Eighth Floor  
San Francisco, California 94111-3834  
Tel: 650-326-2400  
Fax: 650-326-2422  
RLC:crf

60443776 v1



Effective on 12/08/2004.  
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

# FEES TRANSMITTAL For FY 2005

Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** (\$180)

| Complete if Known    |                        |
|----------------------|------------------------|
| Application Number   | 09/471,669             |
| Filing Date          | December 24, 1999      |
| First Named Inventor | Anderson, John P.      |
| Examiner Name        | Walicka, Malgorzata A. |
| Art Unit             | 1652                   |
| Attorney Docket No.  | 015270-006430US        |

**METHOD OF PAYMENT** (check all that apply)

Check  Credit Card  Money Order  None  Other (please identify): \_\_\_\_\_  
 Deposit Account Deposit Account Number: 20-1430 Deposit Account Name: Townsend and Townsend and Crew LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

Charge fee(s) indicated below  Charge fee(s) indicated below, except for the filing fee  
 Charge any additional fee(s) or underpayments of fee(s)  Credit any overpayments  
 under 37 CFR 1.16 and 1.17

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**FEE CALCULATION**

**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

| <u>Application Type</u> | <u>FILING FEES</u>  |                 | <u>SEARCH FEES</u>  |                 | <u>EXAMINATION FEES</u> |                 | <u>Fees Paid (\$)</u> |
|-------------------------|---------------------|-----------------|---------------------|-----------------|-------------------------|-----------------|-----------------------|
|                         | <u>Small Entity</u> | <u>Fee (\$)</u> | <u>Small Entity</u> | <u>Fee (\$)</u> | <u>Small Entity</u>     | <u>Fee (\$)</u> |                       |
| Utility                 | 300                 | 150             | 500                 | 250             | 200                     | 100             | _____                 |
| Design                  | 200                 | 100             | 100                 | 50              | 130                     | 65              | _____                 |
| Plant                   | 200                 | 100             | 300                 | 150             | 160                     | 80              | _____                 |
| Reissue                 | 300                 | 150             | 500                 | 250             | 600                     | 300             | _____                 |
| Provisional             | 200                 | 100             | 0                   | 0               | 0                       | 0               | _____                 |

**2. EXCESS CLAIM FEES**

Fee Description Small Entity  
 Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent Fee (\$) Fee (\$)  
 50 25

Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent Fee (\$) Fee (\$)  
 200 100  
 Multiple dependent claims Fee (\$) Fee (\$)  
 360 180

| <u>Total Claims</u> | <u>Extra Claims</u> | <u>Fee (\$)</u> | <u>Fee Paid (\$)</u> | <u>Multiple Dependent Claims</u> | <u>Fee (\$)</u> | <u>Fee Paid (\$)</u> |
|---------------------|---------------------|-----------------|----------------------|----------------------------------|-----------------|----------------------|
| _____               | -20 or HP = _____   | _____ x _____   | = _____              | _____                            | _____           | _____                |

HP = highest number of total claims paid for, if greater than 20

| <u>Indep. Claims</u> | <u>Extra Claims</u> | <u>Fee (\$)</u> | <u>Fee Paid (\$)</u> | <u>Multiple Dependent Claims</u> | <u>Fee (\$)</u> | <u>Fee Paid (\$)</u> |
|----------------------|---------------------|-----------------|----------------------|----------------------------------|-----------------|----------------------|
| _____                | -3 or HP = _____    | _____ x _____   | = _____              | _____                            | _____           | _____                |

HP = highest number of independent claims paid for, if greater than 3

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

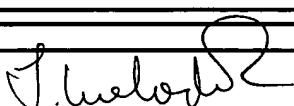
| <u>Total Sheets</u> | <u>Extra Sheets</u> | <u>Number of each additional 50 or fraction thereof</u> | <u>Fee (\$)</u> | <u>Fee Paid (\$)</u> |
|---------------------|---------------------|---|-----------------|----------------------|
| _____               | - 100 = _____       | / 50 = _____ (round up to a whole number)               | _____ x _____   | = _____              |

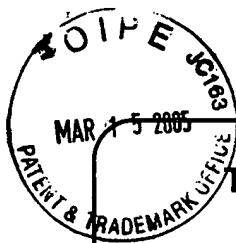
**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount) \_\_\_\_\_

Other: Submission of Information Disclosure Stmt \_\_\_\_\_ 180 \_\_\_\_\_

**SUBMITTED BY**

|                   |   |   |                        |
|-------------------|---|---|------------------------|
| Signature         |  | Registration No. 37,505<br>(Attorney/Agent) | Telephone 650-326-2400 |
| Name (Print/Type) | Joe Liebeschuetz  |   | Date March 15, 2005    |



# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

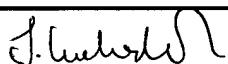
Total Number of Pages in This Submission **7** Attorney Docket Number **015270-006430US****ENCLOSURES (Check all that apply)**

|  |   |   |
|--|---|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form (1 pg., submitted in duplicate)   | <input type="checkbox"/> Drawing(s)                                       | <input type="checkbox"/> After Allowance Communication to TC                            |
| <input type="checkbox"/> Fee Attached  | <input type="checkbox"/> Licensing-related Papers                         | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences     |
| <input type="checkbox"/> Amendment/Reply   | <input type="checkbox"/> Petition   | <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) |
| <input type="checkbox"/> After Final   | <input type="checkbox"/> Petition to Convert to a Provisional Application | <input type="checkbox"/> Proprietary Information  |
| <input type="checkbox"/> Affidavits/declaration(s)   | <input type="checkbox"/> Power of Attorney, Revocation                    | <input type="checkbox"/> Status Letter  |
| <input type="checkbox"/> Extension of Time Request   | <input type="checkbox"/> Change of Correspondence Address                 | <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):         |
| <input type="checkbox"/> Express Abandonment Request   | <input type="checkbox"/> Terminal Disclaimer                              | <input type="checkbox"/> Return Postcard  |
| <input checked="" type="checkbox"/> Supplemental Information Disclosure Statement (2 pages); PTO/SB/08A (1 page) PTO/SB/08B (2 pgs) *copy of cite nos. 155-184 | <input type="checkbox"/> Request for Refund                               |   |
| <input type="checkbox"/> Certified Copy of Priority Document(s)  | <input type="checkbox"/> CD, Number of CD(s) _____                        |   |
| <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application  | <input type="checkbox"/> Landscape Table on CD                            |   |
| <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53  |   |   |

**Remarks** The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

**\*Not included in "Total Number of Pages In this Submission"**

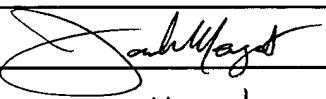
**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

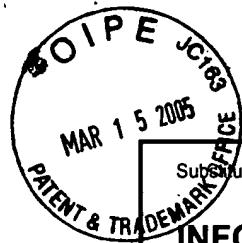
|              |   |          |        |
|--------------|---|----------|--------|
| Firm Name    | Townsend and Townsend and Crew LLP  |          |        |
| Signature    |  |          |        |
| Printed name | Joe Liebeschuetz  |          |        |
| Date         | March 15, 2005  | Reg. No. | 37,505 |

**CERTIFICATE OF TRANSMISSION/MAILING**

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|-----------------------|---|------|---------|
| Signature             |  |      |         |
| Typed or printed name | Jordan Mayat  | Date | 3/15/05 |

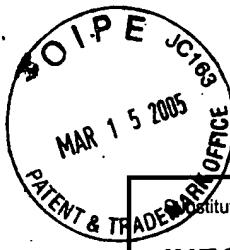


|   |  |                               |           |                                 |                               |
|---|--|-------------------------------|-----------|---------------------------------|-------------------------------|
| <p>Substitute for form 1449A/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(use as many sheets as necessary)</p> |  |                               |           | <p><b>Complete if Known</b></p> |                               |
| <p>Sheet</p>  |  | <p>1</p>                      | <p>of</p> | <p>3</p>                        | <p>Attorney Docket Number</p> |
| <p>DEMARKER</p>   |  | <p>015270-006430US</p>        |           |                                 |                               |
| <p>Application Number</p>   |  | <p>09/471,669</p>             |           |                                 |                               |
| <p>Filing Date</p>  |  | <p>December 24, 1999</p>      |           |                                 |                               |
| <p>First Named Inventor</p>   |  | <p>Anderson, John P.</p>      |           |                                 |                               |
| <p>Art Unit</p>   |  | <p>1652</p>                   |           |                                 |                               |
| <p>Examiner Name</p>  |  | <p>Walicka, Malgorzata A.</p> |           |                                 |                               |

| FOREIGN PATENT DOCUMENTS |                       |                           |                     |                                |   |  |
|--------------------------|-----------------------|---------------------------|---------------------|--------------------------------|---|--|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document   |                     | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited<br>Document | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear |
|                          |                       | Country Code <sup>3</sup> | Number <sup>4</sup> |                                |   |  |
|                          | 170                   | EP                        | 1 445 263           | A1                             | 08-11-2004  |  |
|                          | 171                   | EP                        | 855 442             | A2                             | 07-29-1998  |  |
|                          | 166                   | GB                        | 2 364 059           | B                              | 01-14-2004  |  |
|                          | 167                   | GB                        | 2 389 114           | B                              | 02-04-2004  |  |
|                          | 168                   | GB                        | 2 389 113           | B                              | 02-04-2004  |  |
|                          | 169                   | GB                        | 2 389 182           | B                              | 02-04-2004  |  |
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| Examiner<br>Signature |  | Date<br>Considered |  |
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<sup>1</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>2</sup> Applicant's unique citation designation number (optional). <sup>3</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>4</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>5</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>8</sup> Applicant is to place a check mark here if English language Translation is attached.



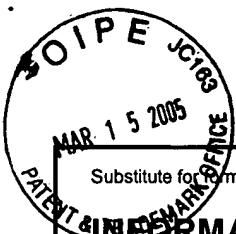
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|------------------------------|---|----|---|--------------------------|------------------------|
| Institute for form 1449B/PTO |   |    |   | <b>Complete if Known</b> |                        |
|                              |   |    |   | Application Number       | 09/471,669             |
|                              |   |    |   | Filing Date              | December 24, 1999      |
|                              |   |    |   | First Named Inventor     | Anderson, John P.      |
|                              |   |    |   | Art Unit                 | 1652                   |
|                              |   |    |   | Examiner Name            | Walicka, Małgorzata A. |
| Sheet                        | 2 | of | 3 | Attorney Docket Number   | 015270-006430US        |

| <b>NON PATENT LITERATURE DOCUMENTS</b> |                       |   |  |                |
|--|-----------------------|---|--|----------------|
| Examiner Initials *                    | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |  | T <sup>2</sup> |
|  | 181                   | BORK, P., "Powers and Pitfalls in Sequence Analysis: The 70% Hurdle," <u>Genome Research</u> , 10:398-400 (2000).   |  |                |
|  | 179                   | BROUN et al., "Catalytic Plasticity of Fatty Acid Modification Enzymes Underlying Chemical Diversity," <u>Science</u> , 282:131-133 (1998).   |  |                |
|  | 178                   | DAS et al., "Estrogenic responses in estrogen receptor- $\alpha$ deficient mice reveal a distinct estrogen signaling pathway," <u>PNAS</u> , 94:12786-12791 (1997).   |  |                |
|  | 183                   | DENNIS et al., "Kunitz Domain Inhibitors of Tissue Factor-Factor VIIa," <u>J. Biol. Chem.</u> , 269(35):22129-22136 (1994).   |  |                |
|  | 155                   | Examination Report for United Kingdom 00121314.9 dated November 1, 2002.  |  |                |
|  | 156                   | Examination Report for United Kingdom 00121314.9 dated July 21, 2003.   |  |                |
|  | 157                   | Examination Report for United Kingdom 00121314.9 dated October 30, 2003.  |  |                |
|  | 158                   | Examination Report for United Kingdom Application 0318112.0 dated November 19, 2003.  |  |                |
|  | 159                   | Search and Examination Report for United Kingdom Application 0318112.0 dated September 24, 2003.  |  |                |
|  | 160                   | Search and Examination Report for United Kingdom Application 0318107.0 dated September 25, 2003.  |  |                |
|  | 161                   | Search and Examination Report for United Kingdom Application 0318113.8 dated September 25, 2003.  |  |                |
|  | 162                   | Examination Report for United Kingdom Application 0318113.8 dated November 19, 2003.  |  |                |
|  | 163                   | Examination Report for European Application 00919298.0 dated October 30, 2003.  |  |                |
|  | 164                   | Search Report for European Application 04006991.6 dated June 11, 2004.  |  |                |
|  | 165                   | Examination Report for New Zealand Application 534876 dated August 27, 2004.  |  |                |
|  | 184                   | International Preliminary Examination Report for PCT application PCT/US00/03819 dated 9/4/02.   |  |                |

|                    |  |                 |  |
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| Examiner Signature |  | Date Considered |  |
|--------------------|--|-----------------|--|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.



Substitute for Form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

|       |   |    |   |                   |
|-------|---|----|---|-------------------|
| Sheet | 3 | of | 3 | Complete if Known |
|-------|---|----|---|-------------------|

Attorney Docket Number 015270-006430US

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials * | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|---------------------|-----------------------|---|----------------|
|                     | 176                   | JACKSON et al., "The p47 <sup>box</sup> Mouse Knock-Out Model of Chronic Granulomatous Disease," <u>J. Exp. Med.</u> , 182:751-758 (1995).  |                |
|                     | 182                   | KICK et al., "Structure-based design and combinatorial chemistry yield low nanomolar inhibitors of cathepsin D," <u>Chem. &amp; Biol.</u> , 4:297-307 (1997).   |                |
|                     | 173                   | KRISTIE, T. M., "The Mouse Homologue of the Human Transcription Factor C1 (Host Cell Factor)," <u>J. Biol. Chem.</u> , 272(42):26749-26755 (1997).  |                |
|                     | 174                   | LI et al., "Cloning and Characterization of Three New Murine Genes Encoding Short Homologues of RNase P RNA*," <u>J. Biol. Chem.</u> , 270(42):25281-25285 (1995).  |                |
|                     | 177                   | RAABE et al., "Knockout of the abetalipoproteinemia gene in mice: Reduced lipoprotein secretion in heterozygotes and embryonic lethality in homozygotes," <u>PNAS</u> , 95:8686-8691 (1998).  |                |
|                     | 172                   | SUN et al., "Gene Structure, Chromosomal Localization, and Expression of the Murine Homologue of Human Proteinase Inhibitor 6 (PI-6) Suggests Divergence of PI-6 from the Ovalbumin Serpins*," <u>J. Biol. Chem.</u> , 270(27): 16089-16096 (1995).             |                |
|                     | 175                   | UMANS et al., "Targeted Inactivation of the Mouse $\alpha$ -Macroglobulin Gene*," <u>J. Biol. Chem.</u> , 270(34):19778-19785 (1995).   |                |
|                     | 180                   | VAN DE LOO et al., "An oleate 12-hydroxylase from <i>Ricinus communis</i> L. is a fatty acyl desaturase homolog," <u>PNBS</u> , 92:6743-6747 (1995).  |                |
|                     |                       |   |                |
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|--------------------|--|-----------------|--|
| Examiner Signature |  | Date Considered |  |
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<sup>1</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>2</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.